

REMARKS

Reconsideration of this application is respectfully requested:

I. Status of the Claims

Claims 1-61 are pending. Claims 1-11, 15, and 17-61 are withdrawn. Applicant has amended claim 16 by deleting “a polypeptide chosen from one or more of STS, HPH2 and” to comply with the finality of the restriction requirement. Applicant has cancelled claims 12-14 without disclaimer or surrender of the subject matter recited therein. New claims 62-77 are presented. Support for these claims includes original claims 12-14. Additional support includes paragraphs [034], [040], [042], and Example 6.

II. Claim Objection

The Office objects to claim 16 because “said claim still recites non-elected subject matter, namely HPH2 and STS” and stated that “Applicant is advised to delete said proteins from claim 16.” Office Action, p. 3.

Applicant has deleted HPH2 and STS from claim 16, and requests that the Office withdraw the rejection.

III. The Claims Are Not Indefinite

A. The Recited Proteins

The Office rejects claims 12-14 and 16 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Office Action, p. 3. According the Office, the term “MK2 polypeptide” in claims 12 and 16 is indefinite because in the disclosure “applicant has defined said term as including variants, fragments, homologues, substitution mutants, addition mutants wherein said variants have MK2 activity.” *Id.* The Office asserts that

“this definition is vague because for example, it is indefinite as to after how many substitutions or additions done to MK2, said polypeptide no longer has ‘MK2 activity.’”

Id. The Office also asserts “[i]t is further unclear as to what are the one or more biological actives of ‘MK2 interacting proteins.’” *Id.* at 4.

Although Applicant respectfully traverses this rejection, in an effort to advance prosecution of this application, Applicant has cancelled claims 12-14, thereby rendering the rejection moot. In so much as the Examiner may consider applying the same rejection to any of the newly presented claims, Applicant respectfully asserts that the newly presented claims comply with 35 U.S.C. § 112, second paragraph.

“The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity.” M.P.E.P. § 2173.02. (emphasis added). The focus of this inquiry is “to determine whether the claim apprises one of ordinary skill in the art of its scope.” *Id.* As stated by the Federal Circuit, “[o]nly when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.” *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004).

Applicant asserts that the claims are not indefinite. The disclosure of the specification describes features of the proteins of the claims that would inform the skilled artisan of the scope of the claims. For example, MK2 is explicitly defined as a “protein described in Stokoe *et al.* (Biochem J. 296: 843-849 (1993)).” Specification, paragraph [040]. Stokoe sets forth the sequence of MK2 in Figure 2. The specification

further describes features of MK2 including “a proline-rich region containing 2 putative SH3-binding sites, a kinase catalytic domain, a threonine residue phosphorylated by MAP kinase, and a nuclear localization signal.” Specification, paragraph [040]. From this description, one of skill in the art could clearly envision the metes and bounds of the claims.

The specification sets forth similar descriptions of the MK2 interacting proteins. For example, the specification provides amino acid sequences of MK2 interacting proteins and sequences of DNAs encoding those proteins. See paragraph [034]. The specification also describes features of the interacting proteins. For example, Figure 8 depicts domains present in the MK2 interacting proteins and Figure 16A provides additional information regarding the structural domains of Shc. Biochemical properties of Shc, such as phosphorylation status, biological activities, and expression levels are also disclosed by the specification. See paragraphs [042-043]. Thus, the specification provides ample description by which the skilled artisan would be apprised of the claims' scope.

Applicant respectfully requests that the Office withdraw the rejection.

IV. The Claims Satisfy Written Description

The Office rejects claims 12-14 and 16 under 35 U.S.C. 112, first paragraph, for alleged failure to satisfy the written description requirement. Office Action, p. 5.

According to the Office Applicant is claiming MK2 polypeptides by “what they do rather than what they are and this kind of definition fails to meet the requirements of 112 first paragraph.” *Id.* at 6.

Although Applicant respectfully traverses this rejection, in an effort to advance prosecution of this application, Applicant has cancelled claims 12-14, thereby rendering the rejection moot. In so much as the Examiner may consider applying the same rejection to any of the newly presented claims, Applicant respectfully asserts that the newly presented claims comply with 35 U.S.C. § 112, second paragraph.

The written description requirement can be met by “describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.” M.P.E.P. § 2163 (quoting *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). In addition, written description is satisfied where the specification discloses a correlation between structure and function. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002).

Applicant respectfully asserts that the disclosure of the application satisfies the written description requirement. When describing MK2, the specification cites a publication that provides the amino acid sequence of MK2. See paragraph [040]. The specification sets forth structural features of the MK2 protein including “a proline-rich region containing 2 putative SH3-binding sites, a kinase catalytic domain, a threonine residue phosphorylated by MAP kinase, and a nuclear localization signal.” Specification, paragraph [040]. The specification discloses the structure of MK2 that mediates binding to Shc. For example, the specification describes mutants of MK2, including an N-terminal truncation comprising amino acids 41-400, a C-terminal truncation comprising amino acids 1-370, and a protein comprising the catalytic domain,

amino acids 41-338. See paragraph [0140]. The specification further discloses that “[t]he interaction profile with Shc A indicates that minimally, Shc A interacts with the MK2 catalytic domain and that deleting the MK2 N-terminus might induce a conformational change such that Shc A no longer binds MK2 efficiently.” Specification, paragraph [0140]. Thus, the specification discloses the structure of MK2 that mediates one of its functions, Shc binding.

The specification also discloses the amino acid sequences of MK2 interacting proteins and the domains that mediate biological functions of those proteins. See Figures 1-6. For example, the description of Shc 2 includes disclosure of structural features including phosphorylation status, biological activities, and isoforms. See paragraphs [042-043]. Moreover, the specification also describes the structures of Shc that correlate with MK2 binding. See, e.g., Figure 15B. Accordingly, the specification satisfies the written description requirement by describing the structures of the molecules of the claimed methods, and discloses a correlation in the structures and functions of the molecules of the claimed method. In light of the disclosure of the specification, one of skill in the art would conclude that Applicant was in possession of the invention when the application was filed. See M.P.E.P. § 2163; see also, *Vas-Cath Inc., v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

Applicant respectfully requests the withdrawal of the rejection.

V. The Claims Are Not Obvious

The Office rejects claims 12-14 under 35 U.S.C. § 103(a) as allegedly unpatentable over Plath, K., *et al.*, “Characterization of the proline rich region of

MAPKAP kinase 2: influence on catalytic properties and binding to the C-ABL SH3 domain in vitro,” Biochemical and Biophysical Research Communications, 203: 1188-94 (1994) (“Plath”) in view of U.S. Patent No. 6,420,338 (Schneider).” Office Action, p. 6. According to the Office, “Plath teaches an assay . . . that detects MA[P]KAP kinase 2 interaction with the Sh3 domain of c-able tyrosine kinase.” *Id.* The Office concedes that “Plath does not teach a screening method wherein its assay method is performed in the presence of modulator.” *Id.* at 7. However, the Office asserts that “once a useful kinase is identified and its substrate is known it is routine to use commonly known kinase inhibitors . . . in order to modulate the activity of said kinase.” *Id.* The Office concludes that “it would have been obvious to one of ordinary skill in the art to start with the assay of Plath and add commonly known modulators of kinases [of Schneider] to the assay mixture.” *Id.*

Although Applicant respectfully traverses this rejection, in an effort to advance prosecution of this application, Applicant has cancelled claims 12-14, thereby rendering the rejection moot. In so much as the Examiner may consider applying the same rejection to any of the newly presented claims, Applicant respectfully asserts that the newly presented claims comply with 35 U.S.C. § 112, second paragraph.

The question of obviousness must be viewed in light of the scope and content of the prior art, differences between the claimed invention and the prior art, and the level of skill in the art. *See Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966); *see also, KSR International Co. v. Teleflex Inc.*, 85 U.S.P.Q.2d 1385 (2007). These factors are considered to determine “whether there was an apparent reason to combine the

known elements in the fashion claimed by the patent at issue.” *KSR*, 85 U.S.P.Q.2d at 1396. The Office has not provided any reason why Plath, Schneider, or their combination would have led the skilled artisan to the claimed invention.

Plath uses an assay to measure the binding of mouse MAPKAP kinase 2 with an isolated SH3 domain, and measures the activity of MAPKAP-2 on hsp25. See Figures 2 and 3. Plath does not disclose a Shc protein. In fact, Plath lists several substrates of MAPKAP kinase 2, none of which are Shc proteins. See p. 1188. Nothing in Plath would lead skilled artisan to a method that includes a Shc protein. Moreover, as admitted by the Office, “Plath does not teach a screening method wherein its assay method is performed in the presence of modulator.” Office Action, p. 7. Accordingly, Plath by itself does not render the claimed methods obvious.

Schneider does not cure the deficiencies of Plath. Schneider discusses kinases belonging to the Src family of kinases and inhibitors of those kinases. See Col. 4, lines 38-46. Schneider does not mention MK2. Schneider mentions an anti-Shc antibody, but does not discuss whether Shc is a substrate of Src or any other kinase. Col. 26, line 30. Accordingly, when considered in view of Plath, Schneider does not provide any reason why the skilled artisan would combine MK2 and Shc to arrive at the claimed method. Accordingly, whether considered alone, or when combined, Plath and Schneider do not render the claimed method obvious.

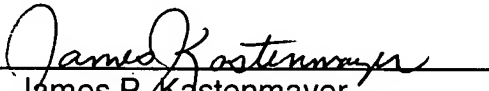
Applicant respectfully requests that the Office withdraw the rejection.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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